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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,825	01/23/2004	Jan Weber	03-100	5021

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER	
KOTINI, PAVITRA	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,825	WEBER ET AL.	
	Examiner	Art Unit	
	Pavitra Kotini	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-13,15,16,24,25,28-32,34-38,50,52,54,56,57,60,61,63,64,71-74 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-23,26,27,33,39-49,51,53, 55,58,59,62,65-70 and 75-79.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/27/05, 6/21/05, 4/11/05, 6/13/03.

DETAILED ACTION

Claims 7, 8, 14, 17-23, 26, 27, 33, 39-49, 51, 53, 55, 58, 59, 62, 65-70, and 75-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant's election of invention I and further of species I (figures 1A-C, 2A-b, & 25) is acknowledged. Contrary to applicant's remarks, claim 53 does not read on the elected species I. The species of figures 13A-B, rather than the figures of 1A-C, 2A-B, 25, discloses the cross-sectional area of the lumen to be 25% greater in the expanded state than in the contracted state. Election was made **without** traverse in the reply filed on 8/18/2006.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9, 12,13, 15, 16, 24, 25, 28, 29, 34, 36-38, 50, 54, 56, 57, 61, 64, 71, 72, and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (US 6514237).

Regarding claim 1, Maseda discloses an elongate body (114, fig. 1), said elongate body having distal (122, fig. 1) and proximal (120, fig. 1) ends and an axis (130, fig. 1); an active region (composite strands; col.4, lines 44-48) comprising a conductive polymer (col.5, lines 1-19) disposed over the elongate body such that the

medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the active region (col.3, lines 50-55).

Regarding claim 2, Maseda discloses that said device comprises two or more active regions (col.3, lines 50-55, multiple composite strands, i.e. 400, fig. 4).

Regarding claim 3, Maseda discloses that said active region expands in at least one radial dimension (col.3, lines 50-55).

Regarding claim 4, Maseda discloses a deformable region (shaft 114) is expanded in said at least one radial dimension upon volumetric expansion of said active region (composite strand 306, fig. 3, 308, fig. 3B; or 400, fig. 4).

Regarding claim 5, Maseda discloses that said active region surrounds said elongate body in the form of a circumferential band (308, fig. 3B; col.6, lines 4-7).

Regarding claim 6, Maseda discloses that said active region is provided in the form of a longitudinal strip (306, fig. 3; col.5, lines 56-58).

Regarding claim 9, Maseda discloses that said active region is disposed in a recess formed in the elongate body (grooves along tubular shaft 114; col.5, lines 58-61).

Regarding claim 12, Maseda discloses that said medical device is a catheter (110, fig. 1).

Regarding claim 13, Maseda discloses that said active region is provided at a distal end of said catheter (col.8, lines 8-9).

Regarding claim 15, Maseda discloses that said catheter is a balloon catheter (110, fig. 1; balloon 118, fig. 1).

Regarding claim 16, Maseda discloses that one or more active regions are disposed such that, upon expansion of the one or more active regions, at least a portion of the balloon is expanded from a first position to a second position that is radially beyond the first position (when a voltage is applied to the composite strands, the composite strands bend and change from an original relaxed position to a activated position; col.5, lines 8-15; col.6 47-51).

Regarding claim 24, Maseda discloses that one or more active regions are disposed such that at least a portion of the length of said medical device is stiffened upon expansion of the one or more of said active regions (col.2, lines 59-62; col.5 line 64- col.6 line 3; col.6 lines 13-17).

Regarding claim 25, Maseda discloses one or more of said active regions circumferentially surround the elongate body (col.6, lines 38-41; col.7 lines 1-4).

Regarding claim 28, Maseda discloses an elongate body(114, fig. 1), said elongate body having distal (122, fig. 1) and proximal (120, fig. 1) ends and an axis (130, fig. 1); a balloon (118, fig. 1); an active region (composite strands; col.4, lines 44-48) comprising a conductive polymer (col.5, lines 1-19), said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state (col.6, lines 45-51).

Regarding claim 29, Maseda discloses said balloon is positioned over at least a portion of said active region (composite strands are placed at distal end where the balloon is attached, hence, balloon is configured to have the composite strand; col.8, lines 8-9).

Regarding claim 34, Maseda discloses at least a portion of the balloon is radially advanced directly by the volumetric expansion of the active region (col.2, lines 25-29; the actuators directly act upon the balloon, probe, or shaft).

Regarding claim 36, Maseda discloses said active region surrounds said elongate body in the form of a circumferential band (col.6, lines 4-7, 38-41; col.7 lines 1-4).

Regarding claim 37, Maseda discloses the active region is provided over said elongate body in the form of a longitudinal member (306, fig. 3, col.5, lines 56-58).

Regarding claim 38, Maseda discloses said active region is disposed in a recess formed in said elongate body (col.5, lines 60-61).

Regarding claim 50, Maseda discloses an insertable body (114, fig. 1) adapted for insertion into a body lumen of a patient; a device lumen (inside shaft 114, fig. 2) within said insertable body; and one or more electrically actuated members disposed along at least a portion of the length of said device lumen (col.6, lines 19-26), said one or more electrically actuated members being adapted to transform at least a portion of the length of said device lumen between (i) an expanded state and (ii) a contracted state in which said insertable body more readily inserted into said body lumen of said patient (col.2, lines 41-62; the electroactive polymer can be manipulated to make it easier to insert the medical device into the body lumen).

Regarding claim 54, Maseda discloses that the one or more electrically actuated members are electroactive polymer actuators (col.2, lines 26-28).

Regarding claim 56, Maseda discloses a single electrically actuated member (col.2, line 36; Maseda expressly states "one" electroactive polymer actuator).

Regarding claim 57, Maseda discloses a plurality of electrically actuated members (col.2, line 36; Maseda expressly states more than one electroactive polymer actuator to be integrated into a device).

Regarding claim 61, Maseda discloses that said one or more electrically actuated members are disposed within said insertable body (306, fig. 3; 400, fig. 4).

Regarding claim 64, Maseda discloses an inflatable balloon (118, fig. 1), wherein the interior of said balloon is in fluid communication with said device lumen (col.4, lines 21-28).

Regarding claim 71, Maseda discloses said deformable region (shaft 114) is an elongated flexible material (col.2, line 28 states the medical device is flexible; fig. 1 shows shaft 114 to be elongated).

Regarding claim 72, Maseda discloses

Regarding claim 80, Maseda discloses that said medical device is balloon catheter (110, fig. 1; col.3, lines 60-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10, 11,30-32, 35, 52, 60, 63, 73, 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 65144237).

Regarding claims 10 and 11, Maseda does not directly teach said recess to be a circumferential recess or a longitudinal recess. However, Maseda does teach a recess (col.5, line 61) and also clearly discloses that various geometric configurations of the composite strands (electroactive polymer actuators), which would fit into the recesses, are possible (col.8, lines 12-15). Maseda states that placement of the composite strands on the device has limitless configurations (col.8, lines 15-16). Hence, if the recesses could be made into various configurations, than the recesses to hold them must also be the same shape. Therefore, it is obvious to a person of ordinary skill in the art, at the time of the invention, that the recess formed in the elongated tubular body of the medical device could be of any shape, including circumferential or longitudinal.

Regarding claims 30, 31, and 32, Maseda does not expressly teach that said active region is adapted to radially advance proximal, central and distal portions of said balloon. However, Maseda does disclose that the active region (composite strands) are located in the balloon (col.8, lines 8-9). If the active regions are radially advanced

elsewhere on the medical device then it is obvious that any portion of the balloon can also be manipulated in the same way. Furthermore, Maseda teaches that since the activation of each strip can be independently controlled, the size and shape of the balloon can be varied (col.6, lines 51-53). Hence it is obvious to a person of ordinary skill in the art, at the time of the invention, that the active region or composite strands taught by Maseda can manipulate or radially advance only the proximal region, or the proximal and distal regions, or all three regions: proximal, central and distal depending on the desired shape.

Regarding claim 35, Maseda does not directly discloses at least a portion of the balloon to be radially advanced by a passive deformable region, and said passive deformable region expanding in at least one radial dimension upon volumetric expansion of said active region. However, Maseda discloses that a mesh material, which is in contact with the active regions, responds and transmits the behavior of the active region to the next active region (col.7, lines 23-31). Hence, this mesh material (702, fig. 7A) acts passively and deforms according to the movement of the active region. Therefore, it is obvious to a person of ordinary skill in the art, at the time of the invention, that the mesh in between the active regions of the balloon qualifies and performs the function of a passive deformable region.

Regarding claim 52, Maseda does not expressly discloses said one or more electrically actuated members extend along only the insertable length of said device lumen. However, Maseda teaches that the present invention's purpose is directed at controlling the medical device which is placed into the body lumen, hence, it is obvious

to have the actuators only along the inserted device lumen. In other words, Maseda teaches that the actuators are placed along the inserted part of the medical device that maneuvered through stenotic lesions and difficult passageways. Hence, it is obvious that the electroactive actuators are only along the insertable medical device.

Regarding claim 60, Maseda does not expressly discloses that one or more electrically actuated members are disposed between the device lumen and the exterior. However, Maseda states that there are various other configurations, including different placement sites for the actuators are possible. The electroactive strands may be incorporated into any portion of the flexible medical device (col.2, lines 63-67). Hence, it is obvious to have actuators between the exterior (114, fig. 2) of the device and the lumen (between 114 and 116, fig. 2).

Regarding claim 63, Maseda does not directly disclose that said insertable body is an extruded body. However, Maseda teaches extruded grooves on the insertable tubular body (co.l.5, line 61). Hence, it is obvious that if the grooves on the body are extruded, then the body must also be extruded.

Regarding claim 73 and 74, Maseda does not expressly disclose that the medical device is stiffened upon radial expansion or longitudinal expansion of said one or more of said active regions. However, Maseda discloses that various dynamic movements can be performed with the electroactive actuators (col.3 lines 55-60; col.8, lines 22-33). Hence, it is obvious that longitudinal and radial expansion, which are basic movements, are achieved by the actuators taught by Maseda.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vito (US 20021033223) discloses an intravascular device for stretching blood vessels with a micro piezo device; Bar-Cohen (US- 5855565) discloses a catheter with expanders and actuators.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pavitra Kotini
AU 3731

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/18/06.